기관고유연구사업 결과보고서

(과제번호 : 0510140)

임상시험을 통한 폐암의 새로운 치료법 개발 Ⅱ

Development Ⅱ of new treatment for lung cancer
by clinical trials

과제책임자 : 이 진 수

국 립 암 센 터

(뒷면)

(측면)

1. 이 보고서는 국립암센터 기관고유연구사업 결과보고서입니다.

2. 이 보고서 내용을 인용할 때에는 반드시 국립암센터 연구사업 결과임을 밝혀야 합니다.

임상시험을 통한 폐암의 새로운 치료법 개발 II

국립암센터

제 출 문

국립암센터 원장 귀하

이 보고서를 기관고유연구사업 “임상시험을 통한 폐암의 새로운 치료법 개발 Ⅱ ” 과제의 결과보고서로 제출합니다.

2007. 12 .

국 립 암 센 터

과 제 책 임 자 : 이 진 수

연 구 원 : 조 재 일

〃 : 김 흥 태

〃 : 한 지 연

〃 : 윤 탁

〃 : 황 보 빈

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(한글) 임상시험을 통한 폐암의 새로운 치료법 개발 Ⅱ

(영문) Development Ⅱ of new treatment for lung cancer by clinical trials

< 요 약 문 >

연구분야(코드)			과제번호	0510140-3
과 제 명	임상시험을 통한 폐암의 새로운 치료법 개발 Ⅱ			
연구기간/연구비 (천원)	합계	2005년 1월 1일 ~ 2007년 12월 31일		480,000
	1차년도	2005년 1월 1일 ~ 2005년 12월 31일		160,000
	2차년도	2006년 1월 1일 ~ 2006년 12월 31일		160,000
	3차년도	2007년 1월 1일 ~ 2007년 12월 31일		160,000
과제책임자	성 명	이진수	주민등록번호	
	전화번호	031-920-1601	전 자 우 편	jslee@ncc.re.kr
색인단어	국문	임상시험, 폐암, 치료법		
	영문	clinical trial, lung cancer, treatment		

◆ 연구목표

<최종목표>

(1) 임상시험을 통한 효과적인 폐암의 새로운 치료법 개발

(2) 임상 연수 교육 과정을 통한 새로운 폐암 치료법 교육

<당해년도 목표>

(1) 기존 임상시험 지속 시행 및 개발

(2) 개발된 protocol 에 따른 임상자료의 수집

(3) 임상연수 교육과정 실시

◆ 연구내용 및 방법

(1) 기존 임상시험 지속 시행 및 개발

2001년부터 2004년 까지 개발된 과제 중 9개 과제는 2005~2007년에 등재 및 진행을 종료하였으며, 2개 과제는 현재 계속 진행 중임.

2005년 10개, 2006년 7개, 2007년4개 과제를 개발함.

(2) 개발된 protocol 에 따른 임상자료의 수집

2001년부터 2004년 까지 개발되어 진행 된 과제 중 논문 11편 (10과제)을 해외 유명 저널에 발표함.

2005년도 이후 개발된 21개 중 11과제는 등재 및 진행을 종료하였으며, 논문 3편 (2과제)을 해외 유명 저널에 발표함.

8편의 과제는 국외 학술대회에서 발표함.

2001년부터 개발된 44개 과제는 대상자 사망 및 질병진행과 관련된 자료를 지속적으로 수집하고 있음.

(3) 임상 연수 교육 과정 신설 준비 및 실시

연구간호사를 대상으로 하는 교육과정을 기획, 준비 하였으며, 폐암연구과 간호사 및 의뢰가 있을 시 타과 연구간호사를 대상으로 교육과정을 실시함.

◆ 연구성과

-정량적 성과

구분	달성치/목표치	달성도(%)
SCI 논문 편수	14/10	140%
IF 합	58.8/30.0	196%

-정성적 성과

1) 새로운 임상시험 프로토콜 개발 및 개발된 프로토콜에 따른 임상자료 수집

(1) 신약의 제1상 임상시험

- 2과제; 2005년 이전 종료, 2006년 논문 발표 (논문 1편)

(2) 새로운 복합항암화학요법의 제2/3상 임상시험

- 8과제; 2005년 이전 종료,6과제 논문 발표 (논문 7편)
- 4과제; 종료, 2과제 논문 발표(논문 3편), 4과제 학술대회 발표
- 7과제; 진행 중

(3) 수술 및 방사선치료와 항암요법을 이용한 복합요법의 제2상 임상시험

- 2과제; 2005년 이전 종료, 2과제 논문 발표 (논문 2편)
- 2과제; 종료, 2과제 학술대회 발표, 논문 준비 중
- 1과제; 진행 중

(4) 다국적 임상 연구

- 2과제;1과제 2005년 이전 종료(학술대회 발표), 1과제 2006년 자진철회
- 5과제; 종료, 1과제 학술대회 발표
- 7과제; 진행 중

(5) 국내 다기관 공동 연구

- 1과제; 2007년 종료
- 3과제; 진행 중

2) 임상 연수 교육과정 실시

- 내용: 폐암의 치료법 2강좌, 임상시험 관련 10강좌
- 대상: 폐암의 임상시험에 관여하는 간호사 - 9명
- 시간: 주 1회 3시간씩 4주 동안 교육 실시 - 총 12강좌로 구성
- 비고: 폐암연구과 연구간호사를 대상으로 _5_회 실시, 타과 연구간호사를 대상으로 _3_회 실시함.

◆ 참여연구원 **(최종연도 참여인원)**	성 명	조재일, 김흥태, 한지연, 윤 탁, 황보빈 이성영, 윤성진, 유선영, 송정은, 추주미, 임은주, 문윤주, 강정은, 김윤정, 최현리, 이옥자, 김진희, 김회라.
	주민등록번호	

Project Summary

Title of Project	Development Ⅱ of new treatment for lung cancer by clinical trials
Key Words	clinical trial, lung cancer, treatment
Project Leader	Jin Soo Lee
Associated Company	None

Objectives:

1. Ultimate object
   (1) Development of new treatment for lung cancer by clinical trials
   (2) Education about the new lung cancer treatment and the clinical trials for Clinical Research Coordinator

2. Object of this year
   (1) Continuance of existing clinical trials and development of new trials.
   (2) Collection of clinical data according to the protocol.
   (3) Preparation and enforcement of clinical trial education programs.

Details and process of Study:

1. Continuance of existing clinical trials and development of new trials.
   (1) 9 of trials developed from 2001 to 2005 have been registered and completed, 2 of them are ongoing.
   (2) We developed 21 studies (10 in 2005, 7 in 2006, 4 in 2007).
2. Collection of clinical data according to the protocol
   (1) 11 papers (10 of trials developed from 2001 to 2005) were published on famous journals.
   (2) 11 of 21 trials developed since 2005 have been completed with all registrations and planned treatment, 3 papers (2 trials) have been published on international famous journals
   (3) 8 of 21 trials were announced at the congress abroad.
   (4) On 44 trials developed since 2001, we've been collecting data related to death and disease progression.
3. Preparation and enforcement of new clinical trial education programs. We've developed the clinical trial education programs. for clinical research coordinator (CRC), and made the instruction to CRCs in lung cancer center and other centers.

Result of Study:

-quantitative outcome

Section	attainment/goal	attainment (%)
Number of SCI papers	14/10	140%
Sum of IF	58.8/30.0	196%

-qualitative outcome

1. Collection of clinical data according to the protocol and development of new trials

(1) Phase I clinical trials.

2 studies completed before 2005, 1 papers published in 2006.

(2) Phase II/III clinical trials of new combination chemotherapies.

8 studies were completed before 2005, 6 studies papers published (7 papers).

4 studies were completed, 2 studies published (3 papers), 4 studies announced at the congress.

7 studies are ongoing.

(3) Phase II clinical trials of concurrent therapy with operation or radiotherapy.

2 studies were completed before 2005, 2 studies published (2 papers).

2 studies were completed, 2 studies announced at the congress abroad (preparing papers).

1 study is ongoing.

(4) Sponsor-Initiated Trials.

1 study was completed before 2005 and announced at the congress.

1 study was withdrawal in 2006.

5 studies were completed, 1 of that was announced at the congress.

7 studies are ongoing

(5) Multicenter Trials

1 study was completed in 2007.

3 studies are ongoing.

2. Planning clinical workshop curriculum

(1) contents: we were developed 2 lectures about treatment of lung cancer and 10 lectures about clinical trials.

(2) recipient: Clinical Research Nurses participate in clinical trials of lung cancer - 9 persons.

(3) schedule: 3 hours a week for every 4 weeks (total 12 lectures)

1. 연구사업의 최종목표

1) 사업 최종 목표

(1) 임상시험을 통한 효과적인 폐암의 새로운 치료법 개발

(2) 임상 연수 교육 과정을 통한 새로운 폐암 치료법 교육

2. 연구사업의 내용 및 결과

1) 새로운 임상시험 프로토콜 개발 및 개발된 프로토콜에 따른 임상자료 수집

(1) 개발된 과제 수 및 등재환자 수

연구 수행 명	개발된 과제 수					등재된 환자 수				
	2001년 ~ 2002년	2003년 ~ 2004년	2005년 ~ 2006년	2007년 (~12/31)	계	2001년 ~ 2002년	2003년 ~ 2004년	2005년 ~ 2006년	2007년 (~12/24)	계
신약의 제1상 임상시험	2	0	0	0	**2**	7	45	0	0	**52**
새로운 복합항암화학요법의 제2/3상 임상시험	7	5	6	1	**19**	167	426	279	113	**985**
수술 및 방사선치료와 항암요법을 이용한 복합요법의 제2상 임상시험	3	1	0	1	**5**	60	99	124	65	**348**
외부수탁과제	1	4	7	4	**14**	5	39	84	27	**155**
다기관임상연구	0	0	4	0	**4**	0	0	157	91	**248**
계	**13**	**10**	**17**	**6**	**44**	**239**	**609**	**644**	**296**	**1788**

(2) 개발된 임상시험 프로토콜 진행현황 및 연구실적현황

연구 수행 명	번호 (NCCCTS 01~07-)	IRB승인일 치료시작일 연구종료일	제 목	실제/목표 환자수(명)	비고
신약의 제1상 임상시험	038	2002.06.05 2002.10.15 **2006.07.31**	악성종양환자 : 헵타플라틴+ 파클리탁셀 : weekly dose 결정을 위한 제 1상 임상시험	33 / 32	04' ASCO초록발표 04' KCA 발표 **05' ASCO 발표** **05' ECCO**
	048	2002.10.31 2002.11.30 2004.05.06	진행성 또는 전이성 비소세포폐암 환자에서 Gemcitabine-vinorelbine -capecitabine 복합항암요법의 제1/2상 임상시험	19 / 39	04' KCA 발표 **06' AJCO 저널발표**
새로운 복합항암 화학요법의 제2/3상 임상시험	006	2001.09.25 2001.10.20 2004.09.30	확장기 소세포폐암 환자에서 weekly irinotecan/cisplatin 복합항암요법의 제2상 임상시험	37/34	02' 내과학회 발표 03' AACR 발표 **05' Medical Oncology 저널발표**
	015	2001.11.01 2001.11.07 2003.10.31	진행성 비소세포폐암 환자에서 docetaxel/capecitabine 복합항암요법의 제2상 임상시험	39/37	02' 암학회 발표 03' ASCO 발표 03' Cancer 저널발표 **05' J.Clin Pathol 저널발표** **05' AACR 발표**
	016	2001.11.01 2002.01.07 2003.10.31	진행성 비소세포폐암 환자에서 docetaxel/capecitabine 복합항암요법의 제2상 임상시험 (previously treated with platinum based chemotherapy)	35/32	04' KCA 발표 **06' JJCO 저널발표**
	023	2001.11.27 2001.12.14 2003.11.30	진행성 비소세포폐암 환자에서 irinotecan/ capecitabine 복합항암요법의 제2상 임상시험 (previously treated with chemotherapy)	37/32	03' AACR 발표 03' CCR 저널발표
	031	2002.02.27 2002.06.12 2003.02.28	확장기 비소세포폐암 환자에서 weekly irinotecan/cisplatin 복합항암요법의 제2상 임상시험	16/37	조기종료 (041 프로토콜시작)

연구 수행 명	번호 (NCCCTS 01~07-)	IRB승인일 치료시작일 연구종료일	제 목	실제/목표 환자수(명)	비고
새로운 복합항암 화학요법 의 제2/3상 임상시험	032	2002.02.27 2002.08.26 2004.09.30	확장기 비소세포폐암 환자에서 weekly irinotecan/cisplatin 복합항암요법의 제2상 임상시험 (previously treated with non-platinum based chemotherapy)	33/32	03' ACOS발표 04' KCA 발표 **06' Cancer 저널발표**
	041	2002.08.12 2002.09.10 2003.06.30	진행성 비소세포폐암환자에서 irinotecan/ cisplatin 복합요법의 약물유전체 및 약동학 연구	81/74	04' ASCO 발표 **05' ASCO 발표** **06' Cancer 저널발표** **06' JCO 저널발표**
	055	2003.02.27 2003.03.05 2006.12.31	확장기 소세포폐암 환자에서 Irinotecan/ cisplatin 유도요법 후 유지요법으로 weekly Irinotecan vs. no further therapy의 무작위배정, 제3상 임상시험	120/110	**07' ASCO 발표** **07' Clinical Cancer research submitted**
	060	2003.07.09 2003.07.18 2007.12.31	전이성 또는 재발성 식도암 환자에서 복합항암요법으로 Irinotecan/cisplatin의 제2상 임상시험	32/33	**06' ESMO 발표** **07' Cancer chemotherpy and pharmacology; 저널발표**
	066	2003.07.04 2003.07.04 2004.06.30	진행성 비소세포폐암(stage IIIB or IV) 환자에서 복합항암요법으로 Irinotecan/ capecitabine 의 제2상 임상시험	53/50	04' ASCO 발표 04' KCA 발표 **05' ASCO 발표** **05' Cancer 저널발표** **05' 11th WCLC 발표**
	069	2003.08.20 2003.08.22 2006.06.30	진행성 또는 전이성 bronchioloalveolar carcinoma(BAC) or 선암의 비흡연 환자를 대상으로 한 Gefitinib(ZD1839; Iressa) 단일군의 제2상 임상연구	72/92	04' AACR 발표 **05' ASCO 발표** **05' KCA 발표** **05' CCR 저널발표** **05' 11th WCLC 발표** **06' JTO 저널발표**

연구 수행 명	번호 (NCCCTS 01~07-)	IRB승인일 치료시작일 연구종료일	제 목	실제/목표 환자수(명)	비고
새로운 복합항암 화학요법의 제2/3상 임상시험	079	2003.11.01 2003.12.11 2006.11.30	비소세포폐암 환자에서 Gemcitabine/Vinorelbine과 Irinotecan/Cisplatin 복합요법의 교차투여, 무작위배정 제2상 임상시험(previously untreated stage IIIB or IV)	146/146	**06' ASCO 발표** **07' Cancer submitted**
	124	2005.02.28 2005.06.10 ~	IB 혹은 II기 비소세포폐암 환자에서 수술 전 선행화학요법과 수술 후 보조화학요법의 제 2상 임상시험	127/148	**진행중**
	155	2005.12.06 2005.12.21 ~	1차 항암화학요법 혹은 항암화학/방사선 병용요법에 실패한 전이성 혹은 재발성 소세포폐암 환자에서 파크리탁셀-젬시타빈 복합화학요법의 제 2상 임상연구	22/33	**진행중**
	156	2005.11.28 2006.02.16 ~	1차 항암화학요법 혹은 항암화학/방사선 병용요법에 실패한 전이성 혹은 재발성 식도암 환자에서 파크리탁셀-카페시타빈(젤로다®) 복합화학요법의 제 2상 임상연구	17/35	**진행중**
	157	2005.11.28 2006.01.02 ~	진행성 (IIIB 혹은 IV기) 비소세포폐암 환자에서 젬자-엘록사틴 복합화학요법의 제 2상 임상연구	20/54	**진행중**
	176	2006.03.08 2006.04.27 ~	확장기 소세포 폐암 환자의 1차 요법으로서 Irinotecan (캠푸토)® / Cisplatin(시스플라틴) 과Simvastatin(심바스타틴)의 병용 투여대한 2상 임상연구	139/61	**진행중**
	177	2006.03.08 2006.05.15 ~	이전 항암치료에 실패한 진행성 비소세포 폐암 환자에서 Gefitinib(이레사)과 Simvastatin(심바스타틴) 병용요법 대 Gefitinib(이레사) 단독요법의 무작위 배정, 2상 임상연구	50/84	**진행중**

연구 수행 명	번호 (NCCCTS 01~07-)	IRB승인일 치료시작일 연구종료일	제 목	실제/목표 환자수(명)	비고
새로운 복합항암 화학요법의 제2/3상 임상시험	285	2007.8.20 시작 예정	항암화학요법에 실패한 소세포폐암 환자에서 2차 요법으로 수텐® (Sunitinib) 단독요법을 이용한 제 2상 임상 연구	0/42	**준비중**
수술 및 방사선 치료와 항암 요법을 이용한 복합 요법의 제2상 임상시험	014	2001.11.01 2001.11.23 2004.10.31	제한기 소세포폐암 환자에서 irinotecan/cisplatin 유도요법 후 하루 2회 방사선 요법과 etoposide/cisplatin 동시 복합요법을 이용한 제2상 임상시험	36/35	03' ASCO 발표 **05' KCA 발표** **05' J Clin Oncol 저널발표** **05' 11th WCLC 발표**
	018	2001.10.30 2002.04.22 2004.04.30	수술이 불가능한 국소 진행성 비소세포폐암에서 gemcitabine/vinorelbine 유도요법 후 경구 etoposide/ cisplatin요법과 방사선 치료의 동시 복합요법을 이용한 제2상 임상시험	42/42	04' ASCO 발표 04' KCA 발표 05' KCA 발표 **05' IJROBP 저널발표**
	040	2002.07.31 2002.08.08 2007.11.08	뇌전이를 동반한 비소세포폐암환자에서 선항암치료-후방사선치료와 선방사선치료-후항암치료의 비교 제3상 임상시험	48/200	**임상시험조기종료** (연구자들의 전뇌방사선치료 기피로 조기종료함.) **07' WCLC 발표** **07' Cancer submitted**
	056	2003.03.25 2003.07.10 2006.06.30	비소세포폐암 환자에서 Irinotecan/cisplatin 항암요법과 방사선 치료의 복합요법 후 Amifostine vs. Epokine군간 비교의 무작위배정, 제2상 임상연구	77/80	**07' ASCO 발표**
	255	2007.04.05 시작예정	수술이 불가능한 제3기 비소세포 폐암환자에서 상피세포 성장인자수용체 (EGFR) 변이 여부에 따른 유도요법 및 방사선-항암제 동시치료에 대한 제2상 임상연구	0/212	**준비중**

연구 수행 명	번호 (NCCCTS 01~07-)	IRB승인일 치료시작일 연구종료일	제 목	실제/목표 환자수(명)	비고
다국적 임상 연구	026	2001.12.27 2002.04.15 2005.01.31	수술 가능한 비소세포폐암 환자에서 선행 화학요법으로 Gemcitabine-Carboplatin - Paclitaxel 복합 요법의 제 2상 시험	10/10	05' ASCO 발표 05' ECCO 발표 **06' J thorac Oncol. 저널 발표**
	072	2003.09.06 2004.05.13 ~	진행성(제3기말) 비소세포 폐암 환자에서 방사선 -항암제(시스플라틴) 병합 치료 후 젬시타빈 단독요법, 젬시타빈+카보플라틴 복합항암요법 혹은 치료없는 관찰군의 무작위 제 2상 임상연구	16/30 (경쟁적 등재)	**등재완료, 진행중**
	076	2003.10.28 2004.01.05 2006.12.31	이전에 항암화학요법을 받았던 진행성 비소세포폐암 환자를 대상으로 한 ALIMTA의 공개형, 단일군 제 2상 임상시험	9/8	05' ASCO 발표 **07' JTO submitted**
	106	2004.07.26 2004.12.02 2005.07.25	항암화학요법을 시행한 악성종양환자에 대한 Palonosetron HCl Inj.의 유효성 및 안전성을 평가하기 위한 Ondansetron Inj.과의 다기관, 무작위배정, 이중맹검, 비교임상시험	18/18	임상시험종료
	108	2004.08.13 2004.10.14 ~	국소진행성 또는 전이성 비소세포 폐암환자를 대상으로 한 ALIMTA와 시스플라틴 병용요법 대 젬자와 시스플라틴 병용요법의 무작위 배정 제3상 임상시험	27/27	follow-up 중 **07' JCO submitted**
	128	2005.04.25 2005.09.02 2007.05.31	진행성 ⅢB/Ⅳ기의 비소세포폐암 환자에 대한 타쎄바TM (엘로티닙)요법의 EXPANDED ACCESS PROGRAM	12/12	**임상시험종료**
	134	2005.06.27 2005.09.07 2007.07.25	진행성 또는 전이성 비소세포폐암 환자에 대한 1차 요법으로써의 Heptaplatin과 Paclitaxel 복합화학요법의 weekly 투여, 제 2상 임상시험	12/33 (경쟁적 등재)	**조기종료** (안전상의 문제 -rug related death)
	154	2005.10.17 자진 철회	화학요법에 실패한 절제불능 NSCLC (흉막 삼출을 보이는 IV기 또는 IIIb기) 성인 환자를 대상으로 1일 1회 경구 투여한 AEE788의 유효성과 안전성을 평가하기 위한 다기관 단일군 제 II상 임상시험	0/10	**자진철회** (안전상의 문제)

연구 수행 명	번호 (NCCCTS 01~07-)	IRB승인일 치료시작일 연구종료일	제 목	실제/목표 환자수(명)	비고
다국적 임상 연구	162	2006.01.16 2006.05.19 2007.09.30	이전 항암치료에 실패한 국소 진행성 또는 전이성 비소세포폐암 환자를 대상으로 알림타®(페메트렉시드)와 벨케이드®(보르테조밉) 병용요법, 알림타 단독요법 및 벨케이드 단독요법의 무작위, 다기관, 공개형 임상시험	1/10 (경쟁적등재)	**임상시험종료**
	163	2006.01.16 2006.09.26 ~	진행성 비소세포폐암 환자의 1차 요법(FIRST-LINE TREATMENT)으로서 Gemcitabine/ Cisplatin과 PF-3512676의 병용투여와 Gemcitabine/ Cisplatin 단독투여에 대한 다국가, 무작위 배정, 공개 투여, 제3상 임상시험	7/10	**등재완료, 진행중**
	192	2006.05.15 2006.09.11 ~	Stage IIIB/IV 의 비소세포폐암 (NSCLC) 환자들에 대한 1차 요법제로서 젬시타빈/플라티늄과 타쎄바®(엘로티닙) 혹은 위약의 연속 병용 투여에 관한 무작위 배정, 위약 대조, 이중 맹검, II 상 임상시험	18/30	**등재완료, 진행중**
	213	2006.08.21 2006.11.29 ~	기존에 Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR TKI) 치료를 받았던, 국소 진행성 또는 전이성(Stage IIIB-IV) 비소세포폐암(NSCLC) 환자에 대하여 'ZD6474(ZACTIMA™) + 최선의 지지 요법' 대 '위약 + 최선의 지지 요법'을 비교하여 그 유효성을 평가하기 위한 제3상, 다국가, 무작위 배정, 이중 맹검, 평행군, 다기관 시험	20/10(경쟁적등재)	**진행중**

연구 수행 명	번호 (NCCCTS 01~07-)	IRB승인일 치료시작일 연구종료일	제 목	실제/목표 환자수(명)	비고
다국적 임상 연구	283	2007.8.20 시작예정	항암화학요법을 받은 적이 없는 Stage ⅢB-Ⅳ 비소세포폐암(NSCLC) 환자에 대한 Carboplatin과 Paclitaxel에 Sorafenib (BAY 43-9006) 병용요법 또는 비병용요법의 안전성과 유효성을 비교하기 위한 무작위 배정 비교 임상시험	0/10	**준비중**
	290	2007.10.22 시작예정	진행성 고형 악성종양 피험자에게 화학요법과 Agonistic anti CD137단일클론 항체 BMS-663513의 병용투여를 위한 제 1상, 다단계 용량증가 시험	0/10	**준비중**
	293	2007.11.19	진행된 NSCLC 환자의 1차 치료에서 타세바®와 아바스틴®의 병용요법과아바스틴®과 화학요법의 병용치료를 비교하기 위한 제 2상 연구	0/4	**준비중**
	297	2007.11.19	국소 진행성 또는 전이성 비소세포폐암(NSCLC)에 대한 백금을 기본 으로 하는 요법 1회 실패 후 도세탁셀 이차요법으로 치료받는 환자에서 Aflibercept와 위약을 비교하는 다국가, 무작위배정, 이중맹검 임상시험	0/8	**준비중**
국내 다기관 공동 임상연구	121	2005.02.21 2005.06.23 ~	근치적 수술을 시행한 식도암 환자에서 수술을 시행한 군과 수술 후 Capecitabine과 Cisplatin 보조 항암화학요법을 시행한 군간의 제 3상 다기관 무작위 비교 임상연구	25/90 (경쟁적 등재)	**진행중** (식도암연구회)
	126	2005.04.25 2005.10.18 ~	비흡연자에서 나타나는 진행성 또는 전이성 폐선암종의 1차 선택 치료로서의 게피티니브(IRESSA™)와 표준화학요법 (Gemcitabine 1250mg/m^{2}와 Cisplatin 80mg/m^2 병용요법)의 비교, 무작위 배정 , 3상 연구	203/314 (경쟁적 등재)	**등재완료, 진행중** (국립암센터(PI), 삼성서울병원, 서울아산병원)

연구 수행 명	번호 (NCCCTS 01~07-)	IRB승인일 치료시작일 연구종료일	제 목	실제/목표 환자수(명)	비고
다기관 임상연구	145	2005.08.22 2005.09.02 2007.05.31	비소세포 폐암 환자에 대한 탈시바(얼로티니브)의 치료효과를 예측하기 위한 유전자 변화에 대한 연구	12/120 (경쟁적 등재)	(대한항암요법연구회)
	203	2006.07.24 2006.08.17 2007.12.18	이전에 항암화학요법을 받았던 진행성 비소세포폐암 환자를 대상으로 한 ALIMTA 단독요법에 관한 임상연구	6/186 (경쟁적 등재)	(대한항암요법연구회)

2) 임상 연수 교육 과정 신설 준비 및 실시

- 대상 : 폐암의 임상시험에 관여하는 간호사 - 10명, 의뢰받은 타 센터 연구간호사 (4명)
- 내용 : 폐암의 치료법 2강좌, 임상시험 관련 10강좌
- 시간 : 주 1회 3시간씩 4주 동안 교육 실시 - 총 12강좌로 구성
- 장소 : 국립암센터 병원동 3층 회의실

강좌	내용
1	폐암치료법의 최신 지견
2	폐암과 임상시험
3	KGCP 및 ICH-GCP
4	임상시험 계획 및 준비, 연구간호사의 역할
5	임상시험 기본 용어 정리
6	IRB 역할
7	대상자 등재 및 동의서
8	이상반응 관리 및 보고
9	자료 수집 및 증례기록서 작성
10	항암요법 및 종양 응급질환
11	임상시험 설계 및 통계적 고려
12	임상시험 자료 분석

- 교육 횟수 : 정규 교육 1회, 신규 연구간호사 교육 9회 (폐암연구과-5회, 타과 4회) 시행

3. 연구결과 고찰 및 결론

(1) 연구 결과 고찰

A Phase Ⅱ Study of Dose-Intensified Weekly Concomitant Administration of Cisplatin and Irinotecan in Chemonaive Patients with Extensive-Disease Small-Cell Lung Cancer (05′ Medical oncology)

Irinotecan/cisplatin (IP) is an active regimen for extensive-disease small-cell lung cancer (ED-SCLC). However, the optimal dose/schedule is unsettled. To evaluate the efficacy and safety of a dose-intensified, weekly concomitant administration of IP, we conducted a phase II study in chemo-naive patients with ED-SCLC. Between October 2001 and February 2004, 37 patients were enrolled. Twenty-nine (78%) were male, 21 (57%) had ECOG PS 0 or 1, and the median age was 62 yr. The initial six patients received cisplatin 50 mg/m2 followed by irinotecan 90 mg/m2 iv on d 1 and 8 of a 21-d cycle (dose level I), with one treatment-related death, three febrile neutropenias. Thereafter, the doses of cisplatin and irinotecan were reduced to 40 mg/m2 and 80 mg/m2, respectively (dose level II). The treatment was continued for up to six cycles. The overall response rate was 97%, with a complete response (CR) rate of 26%. The median duration of response was 6.4 mo (range, 1.6-13.1 mo). At a median follow-up of 27.3 mo, the median survival time was 11.1 mo and 1- and 2-yr survival rates were 44.1% and 11.8%, respectively. The median progression-free survival (PFS) was 6.0 mo (range, 1.5-13.1 mo) and 1-year PFS rate was 7%. Major grade 3 or 4 toxicities included neutropenia (89%), anemia (59%), and diarrhea (27%). Despite of significant myelosuppresion, this dose-intensified weekly concomitant administration of cisplatin and irinotecan was feasible. This dose-schedule showed promising activity with high rate of complete remission in patients with ED-SCLC.

Phase II Study of Irinotecan Plus Cisplatin Induction Followed by Concurrent Twice-Daily Thoracic Irradiation With Etoposide Plus Cisplatin Chemotherapy for Limited-Disease Small-Cell Lung Cancer (05; JCO)

Purpose
Irinotecan plus cisplatin (IP) chemotherapy demonstrated a promising outcome with a high complete response (CR) rate in chemotherapy-naı꾨e patients with extensive small-cell lung cancer (SCLC). We evaluated the efficacy of induction IP chemotherapy followed by concurrent etoposide plus cisplatin (EP) chemotherapy with twice-daily thoracic radiotherapy (TDTRT) in limited-disease SCLC (LD-SCLC).
Results
All 35 patients were assessable for response. The objective response rate was 97% (CR, 3; partial response [PR], 31) after induction chemotherapy and 100% (CR, 15; PR, 20) after concurrent chemoradiotherapy (CCRT). After a median follow-up of 26.5 months, the median survival was 25.0 months (95% CI, 19.0 to 30.9) with 1- and 2-year overall survival rates of 85.7% and 53.9%, respectively. Median progression-free survival (PFS) was 12.9 months with a 1- and 2-year PFS of 58.5% and 36.1%, respectively. The most common toxicities were grade 3 or 4 neutropenia in 68% of patients during induction chemotherapy and 100% during CCRT. Febrile neutropenia occurred in 20% of patients during induction chemotherapy and

60% during CCRT.
Conclusion
IP induction chemotherapy followed by concurrent TDTRT with EP chemotherapy showed a promising activity with favorable 1- and 2-year survival rates. Based on the favorable outcome in this trials, this regimen should be evaluated in a large phase III trial.

Thymidine phosphorylase expression in tumour cells and tumour response to capecitabine plus docetaxel chemotherapy in non-small cell lung cancer (05′ AACR)

Background:
Thymidine phosphorylase (TP) is the key enzyme for capecitabine activation in tumour cells.
Aims:
To examine whether TP expression in tumour cells and stroma is predictive of the tumour response to capecitabine plus docetaxel chemotherapy in patients with advanced non-small cell lung cancer (NSCLC).
Methods:
Tumour samples were available from 30 of 39 patients enrolled in a previous phase II study of capecitabine/docetaxel chemotherapy in patients with advanced NSCLC. Stromal and tumour cell TP expression was evaluated by immunohistochemistry using monoclonal antibody PD-ECGF.
Results:
High tumour cell TP expression was found in 13 of 30 cases and was negatively associated with stromal TP expression ($p = 0.000$). High stromal TP expression was found in 16 of 28 cases and was strongly associated with intense macrophage infiltration ($p = 0.002$), suggesting that macrophages are the major component of TP expression in the stroma. Tumour response to capecitabine/docetaxel was significantly associated with high tumour cell TP expression ($p = 0.004$) and low stromal TP expression ($p = 0.009$). Moreover, high tumour cell TP expression was significantly associated with severe hand-foot syndrome, a toxic side effect of capecitabine ($p = 0.01$). Improved survival was seen for high tumour cell and low stromal TP expression, although results were not significant ($p = 0.6$ and 0.3, respectively).
Conclusions:
In advanced NSCLC, TP expression in tumour cells and stroma is associated with tumour response to capecitabine/docetaxel chemotherapy, and might be a useful predictor of tumour response to capecitabine based chemotherapy. A large scale prospective study is needed to confirm the prognostic significance of TP expression in NSCLC.

Phase Ⅱ Study of Induction Chemotherapy with Gemcitabine and Vinorelbine Followed by Concurrent Chemoradiotherapy with Oral Etoposide and Cisplatin in Patients with Inoperable Stage Ⅲ Non-Small Cell Lung Cancer (05′ IJROBP)

Purpose:
For locoregionally advanced inoperable non-small-cell lung cancer (NSCLC), concurrent chemoradiotherapy has become a standard therapy. We conducted a Phase II trial to examine the efficacy and toxicity of adding gemcitabine and vinorelbine induction chemotherapy to concurrent chemoradiotherapy with oral etoposide and cisplatin.

Methods and materials:
Eligibility included inoperable clinical Stage III NSCLC without pleural effusion, ECOG performance status 0-1, and weight loss < or =5 24 had squamous ca, 12 had adenocarcinoma, and 4 had others. Objective tumor responses were obtained in 29 patients (72.5%), including 18 (45.0%) after induction chemotherapy. After a median follow-up of 23.8 months, the median survival time and progression-free survival was 23.2 months and 10.9 months, respectively, with 2-year survival rate of 43.9%. For the patients with supraclavicular nodal involvement, the median survival time was 11.8 months with 2-year survival rate of 16.7%, whereas the corresponding figures were 27.8 months and 52.0%, respectively, for those without supraclavicular nodal involvement. Toxicity of induction chemotherapy was mild and well tolerated. However, concurrent chemoradiotherapy was associated with G3/4 hematologic toxicity in 75.7%, G3 esophagitis in 24.2%, and two treatment-related deaths. There were nonlife-threatening late toxicities in additional 6 patients.
Conclusion:
Induction chemotherapy with gemcitabine and vinorelbine followed by concurrent chemoradiotherapy with etoposide and cisplatin showed very promising survival in patients with Stage III NSCLC, especially in those without supraclavicular nodal involvement, which warrants further evaluation.

Phase II Study of Weekly Irinotecan plus Capecitabine for Chemotherapy-Naive atients with Advanced Nonsmall Cell Lung Carcinoma (05′ Cancer)

Background:
A Phase II study was conducted to evaluate the efficacy and toxicity of an irinotecan plus capecitabine combination, a new nonplatinum regimen, in chemonaive patients with advanced nonsmall cell lung carcinoma (NSCLC).
Methodes:
Between July 2003 and April 2004, 53 patients with a histologically confirmed diagnosis of NSCLC were enrolled. All but 5 patients were male, 52 (98%) had an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1, 39 (74%) had AJCC Stage IV disease, and the median age was 61 years. Treatment consisted of intravenous irinotecan at a dose of 90 mg/m2 on Days 1 and 8 and oral capecitabine at a dose of 1000 mg/m2 twice daily on Days 1.14 of each 21-day cycle, given up to 12 cycles.
Results:
Of 53 patients enrolled, 22 achieved objective tumor responses (all partial responses) for an overall response rate of 41.5% (95% confidence interval [95% CI], 28.2.54.8%). After a median follow-up of 17.4 months, the median survival was 14.6 months with a 1-year survival rate of 60.1% (95% CI, 46.9.73.4%) and a median progression-free survival of 5.1 months. Treatment was very well tolerated, with only 10% of patients experiencing NCI-CTC Grade 3 or toxicities. The most common toxicities were hand.foot syndrome and diarrhea. In multiple logistic regression analysis for overall response, only the stage predicted for significantly better response (P 0.04). Squamous cell carcinoma was marginally predictive for better response (P 0.08).
Conclusions:
The irinotecan plus capecitabine regimen demonstrated an antitumor activity that is favorably comparable with other commonly used cisplatinbased regimens. Given the mild toxicity profile

and favorable survival outcome, this nonplatinum regimen warrants further evaluation in a randomized trial.

Gefitinib as a First-LineTherapy of Advanced orMetastatic Adenocarcinoma of the Lung in Never-Smokers (06′ JTO)

Purpose:
A subset of patients with adenocarcinoma of the lung who had never smoked cigarettes showed excellent tumor responses to gefitinib therapy.To evaluate the efficacy of gefitinib as a first-line therapy in this subgroup of patients,we conducted a phase II study.
Experimental Design:
Eligible patients hadno smokinghistory, stage IIIBor IVadenocarcinoma, Eastern Cooperative Oncology Group performance status 0 to 2, and adequate organ functions. Treatment consisted of daily oral administration of 250 mg gefitinib for 28 days until disease progression. Responses were assessed after every two cycles of therapy.
Results:
Of 37 patients enrolled, 36were assessed for response. Twenty-five patients (69%) had partial response, 4 (11%) had stable disease, and 7 (19%) had progressive disease. Of10 patients with evaluable brain metastases, 7 had objective responses in both intracranial and extracranial lesions,1had stable disease in the brain and dramatic response in the extracranial lesions, and 2 had progressive disease in both sites. After a median follow-up of 48weeks (range, 4-70weeks), 26 patients had disease progression, with median progression-free survival of 33 weeks, and 9 patients died, all due to disease progression. The median survival time has not been reached yet but the estimated1-year survival rate was73%. Common toxicities were skin rash and mild diarrhea but there was no significant hematologic toxicity.
Conclusions:
Gefitinib showed very dramatic antitumor activity, even in the brain, with unprecedented survivaloutcome innever-smoker adenocarcinoma patients. These data support the use of gefitinib as a first-line therapy in this particular subgroup.

A Pilot Trial of Gemcitabine and Vinorelbine Plus Capecitabine in Locally Advanced or Metastatic Nonsmall Cell Lung Cancer (06′ AJCO)

Objectives:
We conducted a pilot study of gemcitabine, vinorelbine and capecitabine combination to evaluate its toxicity and efficacy in chemo-naive patients with locally advanced or metastatic nonsmall cell lung cancer (NSCLC) after a short phase IB trial. Methods: Eligible chemo-naive patients with stage IIIB or IV NSCLC received outpatient administration of gemcitabine 900mg/m2 and vinorelbine 25 mg/m2 intravenously on days 1 and 8, every 3 weeks, concurrently with capecitabine 1000 mg/m2 given orally twice a day on days 1 to 5 and 8 to 12 (dose level I), or days 1 to 6 and 8 to 13 (dose level II).
Results:
Between November 2002 and December 2003, 19 patients participated in the study at either dose level I (7 patients) or dose level II (12 patients). The maximum tolerated dose, defined as the dose at which no more than 1 of 6 patients in a cohort experienced a dose-limiting

toxicity (DLT) in the first cycle, was not established. However, 1 of 7 patients at dose level I, and 2 of 12 at dose level II experienced DLTs (ie, grade 3 hepatotoxicity in 2 patients, and grade 3 febrile neutropenia in 1 patient). In addition, 2 patients experienced treatment-related pneumonitis requiring mechanical ventilator support after the second course of therapy. Objective tumor response was observed in 5 (26.3%) of 19 patients. Further patient accrual was stopped according to the study design.
Conclusions:
This 3-drug combination showed disappointing antitumor activity against NSCLC with unexpected life-threatening pulmonary toxicity. No further investigation of this regimen is recommended for patients with NSCLC

Randomized Phase II Study of Two Opposite Administration Sequences of Irinotecan and Cisplatin in Patients with Advanced Non small Cell Lung Carcinoma (06, Cancer)

Background:
Combined chemotherapy with irinotecan and cisplatin (IP) is active in patients with nonsmall cell lung carcinoma (NSCLC). However, the optimal administration schedule needs to be defined to maximize its synergic effect. The authors evaluated the efficacy, toxicity, and pharmacokinetics (PK) of IP chemotherapy given on two administration sequences in chemotherapy-naive patients with NSCLC.
Methodes:
Eighty eligible patients were assigned randomly to receive 1 of 2 irinotecan and cisplatin administration sequences on Day 1: irinotecan followed by cisplatin (I-P) (n 39 patients) or cisplatin followed by irinotecan (P-I) (n 41patients). Treatment was comprised of irinotecan at a dose of 80 mg/m2 intravenously on Days 1 and 8 and cisplatin at a dose of 60 mg/m2 intravenously on Day 1 of a 21-day cycle for a maximum of 6 cycles. For PK analysis, serial plasma samples were obtained on Day 1 of the first cycle.
Results:
In total, 77 patients were assessable for efficacy. The overall response rate was 47%, and there was a trend in favor of P-I (54%) compared with I-P (39%). In multivariate logistic regression analysis, the P-I sequence and female gender were found to be significant predictors of a better response (P 0.047 and P 0.011, respectively). Overall toxicity profiles and PK parameters were similar in both arms.
Conclusion:
IP chemotherapy showed promising activity with a favorable 1-year survival rate. For future clinical use, the authors recommend administering cisplatin first and then irinotecan, because that sequence was associated with a higher response rate.

Comprehensive Analysis of UGT1A Polymorphisms Predictive for Pharmacokinetics and Treatment Outcome in Patients With Non-Small-Cell Lung Cancer Treated With Irinotecan and Cisplatin (06, JCO)

Purpose
To determine whether uridine diphosphate-glucuronosyltransferase 1A1, UGT1A7, and UGT1A9 polymorphisms affect the pharmacokinetics (PK) of irinotecan and treatment outcome of Korean patients

with advanced non-small-cell lung cancer (NSCLC).
Methods
Eighty-one patients with advanced NSCLC were treated with irinotecan (80 mg/m2) on day 1 and 8 and cisplatin (60 mg/m2) on day 1 intravenously of each 3-week cycle. Genomic DNA was extracted from peripheral blood and genotyped using direct sequencing. We analyzed the association of UGT1A genotypes with irinotecan PK and clinical outcomes. All statistical tests were two-sided.
Results
In genotype-PK association analysis, UGT1A1*6/*6 (n 6), UGT1A7*3/*3 (n 6), and UGT1A9-118(dT)9/9 (n 11) were associated with significantly lower area under the time-concentration curve (AUC) SN-38G to SN-38 (AUC_{SN-38G}/AUC_{SN-38}) ratio (P .002, P .009, and P .001, respectively). In linkage disequilibrium analysis, the UGT1A7 variants were highly linked with the UGT1A1*6 (D0.85, r 2 0.63) and UGT1A9*22 (D0.95, r 2 0.88), which was substantiated in haplotype analysis. Patients with UGT1A1*6/*6 had lower tumor response and higher incidence of severe neutropenia. UGT1A9-118(dT)9/9 also showed a trend for high incidence of severe diarrhea, but not tumor response. In survival analysis, patients with UGT1A1*6/*6 had significantly shorter progression-free survival (P .001) and overall survival (P .017).
Conclusion
These findings suggest that UGT1A1*6 and UGT1A9*22 genotypes may be important for SN-38 glucuronidation and associate with irinotecan-related severe toxicity. Specifically, UGT1A1*6 might be useful for predicting tumor response and survival outcome of Korean patients with NSCLC treated with irinotecan-based chemotherapy.

A Phase II Study of Irinotecan Plus Cisplatin for Patients With Advanced Stage IIIB or IV NSCLC Previously Treated With Nonplatinum-Based Chemotherapy (06′ Cancer)

Background:
Irinotecan (I) and cisplatin (P) are active chemotherapy agents with clinical synergy in non.small-cell lung cancer (NSCLC). We evaluated the efficacy of IP regimen as a salvage treatment of patients with NSCLC that progressed after nonplatinum-containing regimen(s).
Methodes:
Eligibility required histologically confirmed NSCLC, bidimensionally measurable disease, ECOG PS 0-2, and progressive disease after nonplatinumbased chemotherapy. Treatment consisted of I (65 mg/m2) and P (30 mg/m2) i.v. on Days 1 and 8 of a 21-day cycle, for a maximum of 6 cycles. An informed consent was obtained from all patients.
Results:
Between August 2002 and May 2004, 32 patients with median age of 56 years (range, 42.74) were enrolled. Twenty-four (75%) patients were men, and 28 (88%) had ECOG PS 0 or 1. Twenty-five patients had adenocarcinoma and 6 had squamous-cell carcinoma. All patients were evaluated for response and toxicity, and the response rate was 40.6%. After a median follow-up of 18.5 months, the median survival time was found to be 9.3 months, with a 1-year survival rate of 43.8%. Toxicities were moderate and manageable, with 47% G3 and 9% G4 neutropenia, 19% G3 diarrhea, and 22% G3 asthenia. There was no G4 nonhematologic toxicity.
Conclusions:
The irinotecan and cisplatin combination is an active and well tolerated regimen for the patients with advanced NSCLC that progressed after nonplatinum-containing regimen(s).

A Phase II Trial of Docetaxel Plus Capecitabine in Patients with Previously Treated Non-Small Cell Lung Cancer (06'JCO)

Background:
A combination of docetaxel (T) and capecitabine (X) showed synergistic effects in preclinical studies and phase III randomized trials of metastatic breast cancer. We conducted this phase II study to examine its efficacy in previously treated non-small cell lung cancer (NSCLC) patients.
Methods:
Patient eligibility required advanced NSCLC with measurable lesion(s), at least one prior regimen failure and Eastern Cooperative Oncology Group (ECOG) performance status 0-2. Treatment consisted of T 36 mg/m2 i.v. on days 1 and 8 plus X 1000 mg/m2 p.o. b.i.d. on days 1-14 of a 21-day cycle (level I) or T 30 mg/m2 i.v. on days 1 and 8 plus X 625 mg/m2 p.o. b.i.d. on days 1-14 of a 21-day cycle (level II).
Results:
A total of 35 patients (M/F ¼ 24/11) were enrolled; 29 had received one prior regimen and 19 had received platinum-based regimens. Significant non-hematologic toxicities were observed after the treatment given at level I, including one treatment-related death. Subsequently 29 patients were treated at level II. The treatment at level II was well tolerated with grade 3 or 4 neutropenia only in 10%, grade 3 asthenia in 21% and stomatitis in 14% of patients. Four (15%) of 27 evaluable patients had partial response (PR) at level II and eight (30%) had stable disease (SD).
Conclusions:
The TX regimen showed modest antitumor effects in patients with previously treated NSCLC. For further studies, we recommend T 30 mg/m2 i.v. on days 1 and 8 plus X 625 mg/m2 p.o. b.i.d. on days 1-14 of a 21-day cycle.

Gefitinib is of more benefit in chemotherapy-naive patients with good performance status and adenocarcinoma histology: Retrospective analysis of 575 Korean patients (06' lung cancer)

Summary We analyzed data from 575 patients with advanced or metastatic non-small cell lung cancer treated with gefitinib in National Cancer Center, Goyang, Korea between 2002 and 2005. The overall response rate was 25.7% (95% CI, 22.1.29.6). At a median follow-up of 26 months, the median survival time from the date of gefitinib administration was 10.6 months with 1 year-survival rate of 47.7%. The median survival time calculated from the first diagnosis of advanced/metastatic disease or recurrent disease was 21.6 months. In a multivariate logistic regression model, adenocarcinoma histology, smoking history, performance status, and history of prior chemotherapy were statistically significant predictors for tumor response to gefitinib. The response rate of the most favorable subgroup, chemotherapy-naive never-smokers with adenocarcinoma, was 52.2% (95% CI, 42.6.61.7). In a multivariate Cox proportional hazard model, performance status, adenocarcinoma histology, and history of prior chemotherapy were the independent predictors of survival ($p < 0.001$, $p < 0.001$, and $p = 0.002$, respectively). This retrospective analysis suggests that gefitinib was of great benefit for chemotherapy-naive patients who had good performance status and adenocarcinoma histology. These findings are required to be validated in further prospective clinical studies,

which should include translational research characterizing the molecular predictors.

The Role of Gefitinib Treatment for Korean Never-Smokers with Advanced or Metastatic Adenocarcinoma of the Lung: A Prospective Study (06′ JTO)

Purpose:
This prospective trial was conducted to evaluate the role of gefitinib in never-smokers with advanced or metastatic adenocarcinoma of the lung.
Patients and Methods:
The main inclusion criteria were stage IIIB/IV adenocarcinoma of the lung and status as a lifetime neversmoker. Patients received a 250-mg single oral daily dose of gefitinib until disease progression, unacceptable toxicity, or patient's refusal. Tumor response was assessed after every two 4-week cycles according to the World Health Organization response criteria. Additional analyses were performed to identify predictors of response and survival.
Results:
Between August 2003 and March 2005, 72 Korean patients were enrolled; 55 chemotherapy naive, 17 previously treated; 6 male, 66 female; and ECOG PS 0/1/2, 24/42/4. All patients were assessed for response, toxicity, quality of life, and survival. Overall objective tumor response rate was 55.6% (95% confidence interval [CI], 43.4-67.3%). With a median follow-up of 23 months, the median survival time was 19.7 months (95% CI, 18.5-21.0 months) with a 1-year survival rate of 76.3%. The median duration of response was 6.8 months (95% CI, 4.7-9.0 months). Therapy-related improvement of symptoms and quality of life was observed within 2 to 4 weeks after the commencement of therapy in the responders. In a multivariate Cox proportional hazard model, good performance status and no prior history of chemotherapy were the two significant predictors of better survival (p 0.005 and 0.042).
Conclusion:
Gefitinib showed very promising antitumor activity and survival outcome in Korean never-smokers with adenocarcinoma of the lung. It seems to be a good alternative to standard chemotherapy as a first-line therapy for this subgroup.

A phase II trial of modiWed weekly irinotecan and cisplatin for chemotherapy-naive patients with metastatic or recurrent squamous cell carcinoma of the esophagus (06′Cancer Chemother Pharmacol)

Purpose:
This phase II study assessed the eYcacy and toxicity proWle of a modiWed weekly irinotecan and cisplatin for chemotherapy-naive patients with metastatic/recurrent esophageal squamous cell carcinoma (SQCC).
Methods:
The eligibility criteria included histologically conWrmed esophageal SQCC, no prior chemotherapy, adequate organ functions and written informed consent. Patients received irinotecan 65 mg/m2 plus cisplatin 30 mg/m2 on days 1 and 8, every 3 weeks.
Results:
Thirty-two patients were assessed for response and toxicity. Ten patients achieved a partial response (31.3%; 95% CI, 16.0-50.0%). With a median follow-up of 19.0 months, median progression-free and overall survival was 4.4 and 9.6 months, respectively, with a 1-year

survival rate of 27.4%. Grade (G) 3/4 neutropenia was observed in 50.0% of the patients, which was the most common cause of dose reduction or therapy delay. G3 non-hematologic toxicity included seven (21.9%) asthenias, four (12.5%) diarrheas, and one (3.1%) nausea/vomiting, but no G4 nonhematologic toxicity was observed. Conclusions This modiWed weekly irinotecan and cisplatin failed to ameliorate hematologic toxicity and to improve eYcacy. However, easy administration and favorable non-hematologic toxicity as well as modest anti-tumor activity against metastatic or recurrent esophageal SQCC can make this regimen a potential treatment option, given the complexity of administration and toxicity of conventional infusional 5-FU and cisplatin.

(2) 결론

폐암은 전세계적으로 암 사망률 1위의 가장 치명적인 질환의 하나다. 이에 전 세계적으로 폐암 환자들의 생존율 증가를 위하여 임상시험을 통한 새로운 치료방법이 끊임없이 개발되고 있다. 이에 본 연구 기관에서는 폐암환자의 생존율 증가를 위하여 2002년부터 꾸준히 임상시험을 실시하였고, 다양한 임상시험을 통한 한국인 폐암환자의 생존율을 증가시킬 수 있는 새로운 치료방법을 개발해 왔다. 현재까지 전세계적으로 보고되고 있는 제 2상 임상시험결과와 비교하여 반응률과 생존기간을 상당히 개선시킨 결과를 관찰할 수 있었다. 앞으로 이와 같이 새롭게 개발된 치료방법을 기반으로 우리나라 폐암환자의 치료에 널리 이용될 수 있는 기반을 마련하여, 우리나라 폐암환자의 예후를 개선하고, 나아가 전세계적으로 우수한 암치료 기관으로서의 입지를 마련하고자 한다.

4. 연구성과 및 목표달성도

(1) 연구성과

가. 국내 및 국제 전문학술지 논문 게재 및 신청 **(Investigator Initiated Trials)**

논문명	저자 (저자구분)	저널명 (I.F.)	Vol(No) Page	구분	과제 관련성 (grant)
A Phase Ⅱ Study of Dose-Intensified Weekly Concomitant Administration of Cisplatin and Irinotecan in Chemonaive Patients with Extensive-Disease Small-Cell Lung Cancer (NCC-006)	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Dae Ho Lee, Sung Young Lee, Chun Gun Park, Hae Young Kim, Eun-A Kim, Sung Min Yoon, Hong Gi Lee (공동저자)	Medical Oncology (1.159)	22(3): 281-290, 2005	국외 SCI	상 N02C120
Phase Ⅱ Study of Irinotecan Plus Cisplatin Induction Followed by Concurrent Twice-Daily Thoracic Irradiation With Etoposide Plus Cisplatin Chemotherapy for Limited-Disease Small-Cell Lung Cancer (NCC-014)	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Kwan Ho Cho, Dae Ho Lee, Hyae Young Kim, Eun-A Kim, Sung Young Lee (공동저자)	Journal of Clinical Oncology (10.864)	23(15): 3488-94, 2005	국외 SCI	상 0210140
Thymidine phosphorylase expression in tumour cells and tumour response to capecitabine plus docetaxel chemotherapy in non-small cell lung cancer (NCC-015)	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Eun Kyung Hong, Sung Young Lee, Sung Min Yoon, Dae Ho Lee (공동저자)	Journal of Clinical Pathology (2.966)	58(6): 650-4, 2005	국외 SCI	상 0210140
Phase Ⅱ Study of Induction Chemotherapy with Gemcitabine and Vinorelbine Followed by Concurrent Chemoradiotherapy with Oral Etoposide and Cisplatin in Patients with Inoperable Stage Ⅲ Non-Small Cell Lung Cancer (NCC-018)	Jin Soo Lee (교신저자) Dae Ho Lee (제1저자) Ji-Young Han, Kwan Ho Cho, Hong Ryull Pyo, Hyae Young Kim, Sung Jin Yoon	Internatio-nal Journal Radiation Oncology Biology Physics (4.297)	63(4): 1037-44, 2005	국외 SCI	상 0210140
A Phase Ⅱ study of Weekly Irinotecan plus Capecitabine for Chemotherapy-Naive Patients with Advanced Nonsmall Cell Lung Carcinoma (NCC-066)	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Dae Ho Lee, Sung Young Lee, Chun Gun Park, Hyae Young Kim, Hong Gi Lee, Jae Jin Lee, Heung Tae Kim (공동저자)	Cancer (3.909)	104(12): 2759-65, 2005	국외 SCI	상 0210140, 0510140

논문명	저자 (저자구분)	저널명 (I.F.)	Vol(No) Page	구분	과제 관련성 (grant)
Gefitinib as a Fist-Line Therapy of Advanced or Metastatic Adenocarcinoma of the Lung in Never-Smokers **(NCC-069)**	**Jin Soo Lee (교신저자)** Dae Ho Lee (제1저자) Ji-Youn Han, Hong Gi Lee, Jae Jin Lee, Eun Kyoung Lee, Hyae Young Kim, Hark Kyun Kim, Eun Kyung Hong (공동저자)	Clinical Cancer Research (6.511)	11(8): 3032-37, 2005	국외 SCI	상 0210140
A pilot trial of gemcitabine and vinorelbine plus capecitabine in locally advanced or metastatic nonsmall cell lung cancer **(NCC-048)**	**Jin Soo Lee (교신저자)** Dae Ho Lee (제1저자) Ji-Youn Han, Seong Min Yoon, Jae Jin Lee, Hong Gi Lee, Hyae Young Kim, Sung Jin Yoon, Eun Kyung Hong (공동저자)	Amerian Journal of Clinical Oncology (1.615)	29(2): 143-147, 2006	국외 SCI	상 0210140
Randomized Phase II Study of Two Opposite Administration Sequences of Irinotecan and Cisplatin in Patients with Advanced Nonsmall Cell Lung Carcinoma **(NCC-041)**	**Jin Soo Lee (교신저자)** Ji-Youn Han (제1저자) Hyeong-Seok Lim, Dae Ho Lee, So Young Ju, Sung Young Lee, Hyae Young Kim, Yong-Hoon Park, Chun Gun Park (공동저자)	Cancer (4.434)	106(4): 873-880, 2006	국외 SCI	상 0210130, 0210140
Comprehensive Analysis of UGT1A Polymorphisms Predictive for Pharmacokinetics nad Treatment Outcome in Patients With Non-Small-Cell Lung Cancer Treated With Iriontecan and Cisplatin **(NCC-041)**	**Jin Soo Lee (교신저자)** Ji-Youn Han (제1저자) Hyeong-Seok Lim, Eun Soon Shin, Yeon-Kyeong Yoo, Yong Hoon Park, Jong-Eun Lee, In-Jin Jang, Dae Ho Lee (공동저자)	Journal of Clinical Oncology (11.81)	24(15): 2237-44, 2006	국외 SCI	상 0210130, 0210140, 0510140 0510080
A Phase II Study of Irinotecan Plus Cisplatin for Patients With Advanced Stage ⅢB or Ⅳ NSCLC Previously Treated With Nonplatinum-Based Chemotherapy **(NCC-032)**	**Jin Soo Lee (교신저자)** Heung Tae Kim (제1저자) Ji-Youn Han, Dae Ho Lee, Jong Ho Chun, Hong Gi Lee, Jae Jin Lee, Hyae Young Kim, Sung Young Lee (공동저자)	Cancer (4.434)	107(4): 799-805, 2006	국외 SCI	상 0210240
A phase II trial of docetaxel plus capecitabine in patients with previously treated non-small cell lung cancer **(NCC-016)**	**Jin Soo Lee (교신저자)** Jae Jin Lee (제1저자) Ji-Youn Han, Dae Ho Lee, Hyae Young Kim, Jong Ho Chun, Hong Gi Lee, Seong Min Yoon, Sung Young Lee (공동저자)	Japanese Journal of Clinical Oncology (1.316)	36(12): 761-7, 2006	국외 SCI	상 0210240

논문명	저자 (저자구분)	저널명 (I.F.)	Vol(No) Page	구분	과제 관련성 (grant)
Gefitinib is of more benefit in chemotherapy-naive patients with good performance status and adenocarcinoma histology: Retrospective analysis of 575 Korean patients **(비임상)**	Heung Tae Kim (교신저자) Dae Ho Lee (제1저자) Ji-Youn Han, **Jin Soo Lee (공동저자)**	Lung Cancer (3.172)	53(3): 339-45, 2006	국외 SCI	상 (없음.)
The role of gefitinib treatment for Korean never-smokers with advanced or metastatic adenocarcinoma of the lung: a prospective study **(NCC-069)**	**Jin Soo Lee (교신저자)** Dae Ho Lee (제1저자) Ji-Youn Han, Sun Young Yu, Hyae Young Kim, Byung-Ho Nam, Eun Kyung Hong, Heung Tae Kim (공동저자)	Journal of Thoracic Oncology (NA)	1(9): 965-71, 2006	국외 SCI	상 0210140
A phase II trial of modified weekly irinotecan and cisplatin for chemotherapy naive patients with metastatic or recurrent squamous cell carcinoma of the esophagus **(NCC-060)**	**Jin Soo Lee (교신저자)** Dae Ho Lee (제1저자) Heung Tae Kim, Ji-Youn Han, Hyae Young Kim,Sung Young Lee, Sung Jin Yoon (공동저자)	Cancer Chemotherapy and Pharmacology (2.363)	61(1): 83-8. 2008	국외 SCI	상 0510140

* Grant 0210140 -치료법I

* Grant 0510140 - 치료법II

나. 국내 및 국제 전문학술지 논문 게재 및 신청 **(Sponsored Clinical Trials)**

논문명	저자 (저자구분)	저널명 (I.F.)	Vol(No) Page	구분	과제 관련성
Phase II Trial of Gemcitabine-Carboplatin-Paclitaxel as Neoadjuvant chemotherapy for operable non-small cell lung cancer	Abratt RP, **Lee JS(공동저자), Han JY,** Tsai CM, Boyer M, Mok T, Kim SW, Lee JS, Brnabic AJ, Reece WH, Lehnert M	Journal of Thoracic Oncology (NA)	1(2): 135-40, 2006	국외 SCI	상

다. 국내 및 국제 학술대회 논문 발표

논문명	저자	학술대회명	지역	과제 관련성
Randomized phase Ⅱ study comparing the sequence of irinotecan and cisplatin administration in chemo-naive patients with advanced non-small cell lung cancer	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Dae Ho Lee, Hyae Young Kim, Hong Gi Lee, Jae Jin Lee, So Young Ju, Chun Gun Park (공동저자)	'05 American Society of Clinical Oncology	국외, Orlando, US	상
A Phase I Clinical Study of Weekly Heptaplatin and Paclitaxel in Previously Treated Patients with Advanced Solid Tumor	Jin Soo Lee (교신저자) Kyung Hae Jung (제1저자) Dae Ho Lee, Hark Kyun Kim, Ji-Youn Han, Hyung Suk Lim, So Young Ju, In Jin Jang, Young Suk Park, Jungsl Ro (공동저자)	'05 American Society of Clinical Oncology	국외, Orlando, US	상
A Phase Ⅱ Study of Gefitinib as a First-Line Therapy of Advanced or Metastatic Adenocarcinoma of The Lung in Lifetime Non-smokers	Jin Soo Lee (교신저자) Dae Ho Lee (제1저자) Ji-Youn Han, Hong Gi Lee, Jae Jin Lee, Eun Kyoung Lee, Hyae Young Kim, Heung Tae Kim, Eun Kyung Hong (공동저자)	'05 American Society of Clinical Oncology	국외, Orlando, US	상
A Phase Ⅱ study of Weekly Irinotecan plus Capecitabine for Chemo-naive Patients with Advanced Non-Small Cell Lung Cancer	Jin Soo Lee (교신저자) Heung Tae Kim (제1저자) Ji-Youn Han, Dae Ho Lee, Sugn Young Lee, Chun Gun Park, Hyae Young Kim, Hong Gi Lee, Jae Jin Lee	05' American Society of Clinical Oncology	국외, Orlando, US	상
Intrapatient dose escalation to 800 mg/m2 pemetrexed is safe and feasible in patien s with advanced non-small cell lung cancer (NSCLC) who have had prior chemotherapy	Jin Soo Lee (제1저자, 교신저자) T.C. Hsia, C.H. Yang, D.S. H대, G.C. Chang, K. Park, S.W. Kim, H. Yildirim, W.H. Reece, M. Lehnert (공동저자)	'05 American Society of Clinical Oncology	국외, Orlando, US	상
Phase Ⅱ trial of gemcitabine-carboplatin-paclitaxel (GCP) as neo-adjuvant chemotherapy for operable non-small cell lung cancer (NSCLC)	R.P. Abratt (제1저자, 교신저자) J.S. Lee, J.Y. Han, C.M. Tsai, M. Boyer, T. Mok, S.W. Kim, J.S. Lee, A.J. Brnabic, M. Lehnert (공동저자)	'05 American Society of Clinical Oncology	국외, Orlando, US	상
Thymidine phosphorylse expression in tumor cells and tumor response to capecitabine plus docetaxel chemotherapy on non-small cell lung cancer	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Eun Kyung Hong, Sung Young Lee, Sung Min Yoon, Dae Ho Lee, Heung Tae Kim (공동저자)	'05 American Associaton for Cancer Research	국외, Anaheim, US	상

논문명	저자	학술대회명	지역	과제 관련성
Gefitinib as First-line Therapy of Advanced or Metastatic Adenocarcinoma of the Lung in Never-smokers	Jin Soo Lee (교신저자) Dae Ho Lee (제1저자) Ji-Youn Han, Eun Kyoung Lee, Hyae Young Kim, Heung Tae Kim, Eun Kyung Hong (공동저자)	11th World Conference on Lung Cancer	국외, Barcelona, Spain	상
Phase Ⅱ Study of Irinotecan/Cisplatin Induction Followed by Concurrent Twice-daily Thoracic Irradiation with Etoposide/Cisplatin Chemotherapy for Limited Disease Small Cell Lung Cancer	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Kwan Ho Cho, Dae Ho Lee, Hyae Young Kim, Eun-A Kim, Sung Young Lee (공동저자)	11th World Conference on Lung Cancer	국외, Barcelona, Spain	상
A Phase Ⅱ study of Weekly Irinotecan plus Capecitabine for Chemo-naive Patients with Advanced Non-Small Cell Lung Cancer	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Dae Ho Lee, Sugn Young Lee, Chun Gun Park, Hyae Young Kim, Hong Gi Lee, Jae Jin Lee	11th World Conference on Lung Cancer	국외, Barcelona, Spain	상
Phase Ⅱ trial of neo-adjuvant gemcitabine-carboplatin-paclitaxel (GCP) chemotherapy for operable non-small cell lung cancer (NSCLC)	R.P. Abratt (제1저자, 교신저자) J.S. Lee, J.Y. Han, C.M. Tsai, M. Boyer, T. Mok, S.W. Kim, J.S. Lee, A.J. Brnabic, M. Lehnert (공동저자)	European Cancer Conference	국외, Paris, France	상
A Phase Ⅰ clinical study of weekly heptaplatin and paclitaxel in previously treated patients with advanced solid tumor	Jin Soo Lee (교신저자) Heung Tae Kim (제1저자) Dae Ho Lee, Kyung Hae Jung, Ji-Youn Han, In Jin Jang, Hyung Suk Lim, Sun Hwa Park, Young Suk Park, Jungsl Ro (공동저자)	European Cancer Conference	국외, Paris, France	상
Gefitinib as First-line Therapy of Advanced or Metastatic Adenocarcinoma of the Lung in Never-smokers	Jin Soo Lee (교신저자) Dae Ho Lee (제1저자) Ji-Youn Han, Eun Kyoung Lee, Hyae Young Kim, Heung Tae Kim, Eun Kyung Hong (공동저자)	'05 Korea Cancer Association	국내, 서울	상
Phase Ⅱ Study of Irinotecan/Cisplatin Induction Followed by Concurrent Twice-daily Thoracic Irradiation with Etoposide/Cisplatin Chemotherapy for Limited Disease Small Cell Lung Cancer	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Kwan Ho Cho, Dae Ho Lee, Hyae Young Kim, Eun-A Kim, Sung Young Lee (공동저자)	'05 Korea Cancer Association	국내, 서울	상

논문명	저자	학술대회명	지역	과제 관련성
Phase Ⅱ Study of Induction Chemotherapy with Gemcitabine and Vinorelbine Followed by Concurrent Chemotherapy with Oral Etoposide and Cisplatin in Patients with Inoperable Stage Ⅲ NSCLC	Jin Soo Lee (교신저자) Dae Ho Lee (제1저자) Kwan Ho Cho, Ji-Young Han, Hong Ryull Pyo, Hyae Young Kim, Sung Jin Yoon	'05 Korea Cancer Association	국내, 서울	상
Randomized Phase Ⅱ Cross-over Sequential Chemotherapy Trial of Gemcitabine/Vinorelbine (GV) vs. Irinotecan/Cisplatin (IP) in Patients with Chemo-naïve Stage Ⅲb/Ⅳ Non-Small Cell Lung Cancer	Jin Soo Lee (제1저자, 교신저자) Dae Ho Lee, Ji-Youn Han, Jae Jin Lee, Sun Hwa Park, Jeong Eun Song, Hyae Young Kim, Heung Tae Kim (공동저자)	'06 American Society of Clinical Oncology	국외, Atlanta, US	상
Phase Ⅱ Trial of Weekly Irinotecan and Cisplatin for Chemotherapy-naïve Patients with Metastatic or Recurrent Squamous Cell Carcinoma of The Esophagus	Jin Soo Lee (교신저자) Dae Ho Lee (제1저자) Ji-Youn Han, Sun Young Yu, Eun Ju Lim, Hyae Young Kim, Heung Tae Kim (공동저자)	European Society for Medical Oncology	국외, Istanbul, Turkey	상
The progress of small cell lung cancer management using irinotecan plus cisplatin chemotherapy	Jin Soo Lee(교신저자), Ji-Youn Han (제1저자) Sun Young Yu, Sung Jin Yoon, Eun Ju Lim, Hong Ryull Pyo, Hyae Young Kim, Dae Ho Lee, Geon Kook Lee, Heung Tae Kim, Kwon Ho Cho (공동저자)	'07 American Society of Clinical Oncology	국외, Chicago, US	상
Frontline cytotoxic chemotherapy (CTx) for newly diagnosed non-small cell lung cancer (NSCLC) patients presenting with brain metastasis compared to whole brain radiotherapy (WBRT): Result of a randomized pilot study.	Dae Ho Lee, Sung Jin Yoon, Ji-Youn Han, Heung Tae Kim, Hong Ryull Pyo, Kwan Ho Cho, Sang-Hoon Shin, Heon Yoo, Seung-Hoon Lee, Jin Soo Lee	12th World Conference on Lung Cancer	국내, 서울	상

다. 산업재산권

구분	특허명	출원인	출원국	출원번호
없음.				

※구분 : 발명특허, 실용신안, 의장등록 등

라. 저 서

저서명	저자	발행기관(발행국, 도시)	쪽수	Chapter 제목, 쪽수 (공저일 경우)
Lung Cancer	Ji-Youn Han, Dae Ho Lee, Jin Soo Lee	Ireland	23	Treatment of bronchioloalveolar carcinoma (2007.9월 출판)

마. 연구성과의 정부정책 기여

보고서명	정부정책	기여내용
없음.		

바. 기타연구성과

없음.

(2) 목표달성도

가. 연구목표의 달성도

최종목표	연차별목표		달성내용	달성도(%)	
				연차	최종
임상시험을 통한 효과적인 폐암의 새로운 치료법 개발	1차년도	기존 임상시험 지속 시행 및 임상자료의 수집	2004년 까지 개발 과제 중 2005년에 4개 과제는 종료, 8개 과제는 진행 중임.	100	40
		기존 임상시험의 연구실적 발표	국외 저널발표 6편, 2006년 발표 예정 3편, 게재 심사 중 2편임. 국외 학술대회 발표 12편, 국내 학술대회 발표 3편임.		
		새로운 치료법 개발을 위한 임상시험의 기획	임상시험 10개 과제 개발 및 진행 중임.		
	2차년도	기존 임상시험 지속 시행 및 개발	2005년까지 개발된 과제중 2개 과제 종료, 16개 과제는 진행 중이며, 7개의 과제를 개발함.	100	70
		개발된 protocol 에 따른 임상자료의 수집	국외 저널발표 7편임. 국외 학술대회 발표 2편임.		
	3차년도	기존 임상시험 지속 시행 및 개발	개발되어 진행되고 있는 23개 과제의 지속 수행 및 폐암의 새로운 기전 약물에 대한 치료법 개발 예정임.	100	100
		개발된 protocol 에 따른 임상자료의 수집	담당연구간호사에 의해 자료를 수집하며, 자료에 대한 검증과정을 체계화, 분석에 대한 전문가의 투입 예정임.		
임상 연수 교육 과정을 통한 새로운 폐암 치료법 교육	1차년도	임상 연수 교육 과정 기획	국내 교육과정 조사 및 향후 교육과정 기획 중임.	60	10
	2차년도	임상 연수 교육 과정 신설 준비 및 실시	폐암연구과 연구간호사를 대상으로 교육과정을 실시함.	60	40
	3차년도	임상연구 교육과정 실시	국외 전문기관에 우수 인력을 파견하여 연수과정을 거친 후 원내 교육과정을 실시할 예정임.	80	80

나. 평가의 착안점에 따른 목표달성도에 대한 자체평가

평가의 착안점	자 체 평 가
기존 임상시험이 지속적으로 잘 진행되고 있는가.	대상자 등재가 원활하게 되고 있으며, 각 과제의 자료는 담당자에 의해 수집되고 있음.
기존 임상시험의 연구실적이 논문으로 발표준비가 원활하게 되고 있는가.	대부분의 종료된 과제는 학회발표 및 논문으로 발표가 되었음. 현재 4개의 과제(NCC-040, 055, 056, 079)는 2008년 논문 발표를 목표로 준비 중에 있음.
새로운 치료법 개발을 위한 임상시험의 기획이 원활한가.	외부수탁 및 다기관 임상연구의 개발이 원활하였으며, 제한기 및 확장기 소세포폐암의 치료법에 대한 후속 과제 개발의 개발이 원활하게 이뤄짐.
임상 연수 교육 과정 기획이 진행되었는가.	기획 폐암연구과 연구간호사를 대상으로 교육과정이 진행되었으며, 주기적으로 심도있는 교육 과정이 필요함.

다. 진행된 연구사업에 관한 자체 평가

(1) 임상시험에 관한 인프라 구축

- 연구자주도 임상시험 계획, 시행 및 논문 발표
- 국내 다기관 공동연구 기획, 연구자원 확보 및 성공적 시행

  (예:NCC-126: IRESSA vs. GP)
- 다국적 2/3상 임상시험 유치

(2) LCRG 등 다국적 공동 연구 기반 구축

(예: NCC-072, NCC-192)

(3) 국제 경쟁력 확보

- 다국적 제약회사 주도 임상연구 책임연구자 선정 (NCC-213, Zactima)
- 새로운 항암제 제 1상 연구기관 선전 (NCC-290; BMS-663513)
- 새로운 표적 치료 항암제 (i.e.: BIBW 2992)의 Front line phase II 임상시험 시행기관으로 선정
- 다국적 임상시험 제1 저자로 선정 (NCC-192)

5. 연구결과의 활용계획

(1) 연구종료 2년 후 예상 연구성과

구 분	건 수	비 고
학술지 논문 게재	6	NCC-040, 055, 056, 079 외

* 논문 게재 준비 과제

논문명 (과제번호)	저자 (저자구분)	저널명 (I.F.)	Vol(No) Page	구분	과제 관련성
Primary chemotherapy for newly diagnosed non-small cell lung cancer patients with synchronous brain metastases compared with whole brain radiotherapy first: Result of a randomized pilot study (NCC-040)	Dae Ho Lee, MD(제1저자) **Jin Soo Lee, MD (교신저자)** Han, MD, Heung Tae Kim, MD, Sung Jin Yoon, BS, Hong Ryull Pyo, MD, Kwan Ho Cho, MD, Sang-Hoon Shin, MD, Heon Yoo, MD, Seung-Hoon Lee, MD (공동저자)	Cancer	Submitted	국외 SCI	상
Randomized phase II study of maintenance irinotecan therapy versus observation following induction chemotherapy with irinotecan and cisplatin in extensive disease small cell lung cancer (NCC-055)	Jin Soo Lee (교신저자) Ji-Youn Han (제1저자) Heung Tae Kim, Kun Young Lim, Sung Jin Yoon, Dae Ho Lee, Geon Kook Lee, Eun Kyung Hong (공동저자)	Clinical Cancer Research	Submitted	국외 SCI	상
Randomized phase II study of irinotecan plus cisplatin versus gemcitabine plus vinorelbine as the first-line chemotherapy with second-line crossover in patients with advanced non-small cell lung cancer (NCC-079)	Ji-Youn Han(제1저자) Jin Soo Lee (교신저자) Dae Ho Lee, Jung Eun Song, Sun Hwa Park, Sung Young Lee, Heung Tae Kim, Hyae Young Kim (공동저자)	Cancer	Submitted	국외 SCI	상

(2) 연구성과의 활용계획

본 연구를 통하여 연구자들은 기존에 알려진 항암치료 방법 외에 효과적인 새로운 치료방법을 다양하게 개발하였고, 특히 암환자 치료 수준의 향상과 더불어 예후가 불량한 진행성 폐암환자들의 예후를 개선하여 왔다. 이와 같은 연구결과는 국내외 유수 학회 및 세계적인 해외 논문의 발표를 통하여 그 결과를 인정받았다. 앞으로 본 연구자들은 임상시험을 통하여 새로운 치료방법을 계속 개발하여 전 세계적으로 인정받는 임상시험 선도기관으로서의 입지를 구축할 예정이다.

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